

JUL 17 2003

K031767 P1/2

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

The assigned 510(k) number is: _____

Contact Person: Donna A. Crawford
Director, Corporate Regulatory Affairs
Mentor Corporation
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Santa Barbara, CA 93111

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Date Prepared: June 6, 2003

Device Name and Classification

Proprietary Name: Mentor ObTape Trans-obturator Tape and Introducers
Common Name: Pubourethral Support Sling
Classification Name: Surgical Mesh, polymeric
Class: Class II
Product Code: FTL
CFR #: §878.3300

Device Description

Mentor ObTape Trans-obturator Tape is an implantable, suburethral, support tape indicated for the surgical treatment of all types of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

ObTape is made from non-woven polypropylene fibers. This structure gives the ObTape resistance to traction, tissue colonization and facilitates positioning during surgery. Disposable and re-usable Introducer Needles necessary for the implantation are also available with the device.

Similar to Johnson and Johnson's Tension Free Vaginal Tape (TVT) System cleared under 510(k) No: K974098 and American Medical Systems' Sparc Sling System cleared under 510(k) K013355, ObTape will be manufactured from polypropylene material.

Substantial Equivalence Claim

The Mentor ObTape Trans-obturator Tape is substantially equivalent in material, function, performance and design to the urethral support tape products manufactured and marketed by Johnson & Johnson, 510(k) No: K974098 and American Medical Systems, 510(k) K013355.

Indications for Use

Mentor ObTape Trans-obturator Tape is an implantable, suburethral, support tape indicated for the surgical treatment of all types of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Summary of Testing

All mechanical testing specifications comply with established EDANA standards for Tear Strength, Tensile Strength, and Elongation.

All biocompatibility testing comply with established USP, ISO 10993 or EN standards for Cytotoxicity, Genotoxicity, Hemolysis, Implantation, Pyrogenicity, Intracutaneous, Sensitization, and Systemic Toxicity.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2003

Ms. Donna Crawford
Director, Corporate Regulatory Affairs
Mentor Corporation
201 Mentor Drive
Santa Barbara, California 93111

Re: K031767

Trade/Device Name: Mentor ObTape Trans-obturator Tape and Introducers
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: June 6, 2003
Received: June 10, 2003

Dear Ms. Crawford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K031767

510(k) Number (if known): _____

Device Name: Mentor ObTape Trans-obturator Tape and Introducers

Indications for Use:

Mentor ObTape Trans-obturator Tape is an implantable, suburethral, support tape indicated for the surgical treatment of all types of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

or

Over the Counter Use

(Per CFR 801.109)

(Optimal Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031767